

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 38.80062/001	FOR FURTHER ACTION	See item 4 below
International application No. PCT/GB2004/001156	International filing date (<i>day/month/year</i>) 18 March 2004 (18.03.2004)	Priority date (<i>day/month/year</i>) 18 March 2003 (18.03.2003)]
International Patent Classification (IPC) or national classification and IPC ⁷ A61F 2/06		
Applicant VERYAN MEDICAL LIMITED		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).
2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input checked="" type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input checked="" type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

<p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 740 14 35</p>	<p>Date of issuance of this report 23 September 2005 (23.09.2005)</p> <p>Authorized officer Nora Lindner</p> <p>Telephone No. +41 22 338 89 65</p>
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PATENT COOPERATION TREATY

REC'D 14 JUL 2004

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT WFO PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/001156

International filing date (day/month/year)
18.03.2004

Priority date (day/month/year)
18.03.2003

International Patent Classification (IPC) or both national classification and IPC
A61F2/06

Applicant
VERYAN MEDICAL LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/001156

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/001156

Box No. II Priority

1. ☒ The following document has not been furnished:

- ☒ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2,3,6,7,13,25-27
	No: Claims	1,4,5,8-12,14-24
Inventive step (IS)	Yes: Claims	
	No: Claims	2,3,6,7,13,25-27
Industrial applicability (IA)	Yes: Claims	1-27
	No: Claims	

2. Citations and explanations
- see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO00/38591

D2: EP1269935

D3: WO00/48530

1. Independent claims **1, 4, 14, 17, 20, 22, and 25** do not fulfill the requirements of Article 33(2) PCT because their subject-matter is not novel.
 - a. Document D1 discloses a graft comprising flow tubing having a tubing portion defining a flow lumen (abstract), the flow lumen of said tubing portion being substantially free of ribs or grooves (p. 9, l. 4, 5: tube 11 may have internal ridging or grooving, but not necessarily), wherein the centre line of the flow lumen follows a substantially helical path (p. 9, l. 4, 5: twist; Fig. 3) with a helix angle less than or equal to 65° (p. 3, l. 14, 15), and wherein the amplitude of the helix is less than or equal to one half of the internal diameter of the tubing portion (Fig. 3). Thus, claim **1** is not novel.
 - b. The same document D1 discloses also the additional subject-matter of claim **4**, i.e. the wall having a helical portion so as to resist reduction of the amplitude of the helical centre line (p. 4, l. 8, 9: the thread imparting helical formation constitutes a helical portion).
 - c. The same document discloses or at least suggests the production methods of claims **14, 17, 20, 22, and 25** (p. 4, l. 5-17).
 - d. Note that also document D2 anticipates the subject-matter of claims **1** and **4** and of dependent claims 5-12 (cf. international search report and references cited therein).
2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim **3** does not involve an inventive step in the sense of

Article 33(3) PCT. The subject-matter of claim 3 differs from claim 1 in that the amplitude of the helical centre line is more than or equal to 0.05 of the internal diameter of the tubing portion. Although this parameter is not disclosed in D1 it can be directly derived from Fig. 3 without any inventive activity.

3. Dependent claims **2, 5-13, 15, 16, 18, 19, 21, 23, 24, 26, and 27** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty or inventive step, see documents D1, D2, and D3 and the corresponding passages cited in the search report.

Re Item VII

Certain defects in the international application

1. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 is not mentioned in the description, nor is this document identified therein.

Re Item VIII

Certain observations on the international application

1. Although claims **1, 3, and 4** on one hand and claims **14, 17, 20, 22, and 25** on the other hand have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it

difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, claims **1, 3, 4, 14, 17, 20, 22, and 25** do not meet the requirements of Article 6 PCT.

2. The present application does not fulfill the requirements of Article 6 PCT because the expression "flow lumen ... free of ribs or grooves" in claims **1** and **4** is not clear. So the helical portion 6 of Fig. 4 does define a rib in the flow lumen. If one considers the envelope 5 of the tube as nominal diameter of the tube then the helical portion 6 constricts this diameter locally, thereby creating a protrusion in the flow lumen, which constitutes a "rib" in the broadest sense of this term.